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IRB Update

JULY 2013

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Adding Research Team Members who are not National Jewish Health Employees

Wendy Charles, MS, CIP, CCRP, Director, Research Regulatory Affairs
Justine Knight, Human Resources Assistant

With collaborative research, it is common to include non-NJH employees as members of the research team. For regulatory oversight, the IRB requests the same education certification, credentials, and COI disclosure as they would of a National Jewish Health employee.

There is additional institutional oversight, though, when researchers who are not employees would like to assist with research on the National Jewish Health campus. Our institution must ensure the safety of our patients, employees, and guests, as well as protect the confidentiality of health information and intellectual property.

The Human Resources Department offers a few options that can allow persons who are not employees to assist with research on campus. Specifically, the researchers can be classified as short term or long term affiliates, depending on the duration of planned activities. Affiliates will receive a basic orientation, basic health screening, identification badge, and parking pass at no charge.

To get started:

1) Review information about the *Affiliate Process* on the Human Resources webpage: http://spyderweb.njrc.org/HRweb/HRWEB/Employment%20Home.htm. The website provides the necessary forms to register affiliates. Feel free to telephone Justine Knight (x1035) with questions about the best category to classify the researcher.
2) Schedule an appointment for the researcher to see Human Resources and Employee Health before participating on campus (x1035 or x1412).
3) Turn in the required forms to Justine Knight or Lynne Kjelden (both in G113) at least 48 hours prior to the researcher's appointment.

For more information, contact:
Justine Knight
KnightJ2@njhealth.org
303-398-1035

CONTACT US

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Changes to Funding Sources

Wendy Charles and Deb Clayton

The National Jewish Health Institutional Review Board tracks the sources of research funding to ensure that the appropriate regulations are applied, to ensure that research subjects are adequately informed in consent forms, and to verify congruence between funding proposals and protocols, as documented on Internal Grant Request forms (IGRs).

When a funding source changes, the IRB will now require formal submission of an amendment. The change in funding source can be documented in a memo with a Change/Update cover page.

Additionally, for all IRB-approved studies that are still enrolling subjects at the time the funding source changes, changes to the informed consent document(s) to reflect new funding are also required. Please submit with a Change to Protocol and/or Consent form cover page.

When submitting IGRs that reflect a change in funding source, please be sure to include the appropriate amendment forms with the IGRs.

For more information, contact:
Wendy Charles
charlesw@njhealth.org
303-398-1855

National Jewish Health IRB Mid-Year Metrics

Wendy Charles

Since January 2010, the National Jewish Health IRB has been tracking turnaround times for each submission to the IRB.

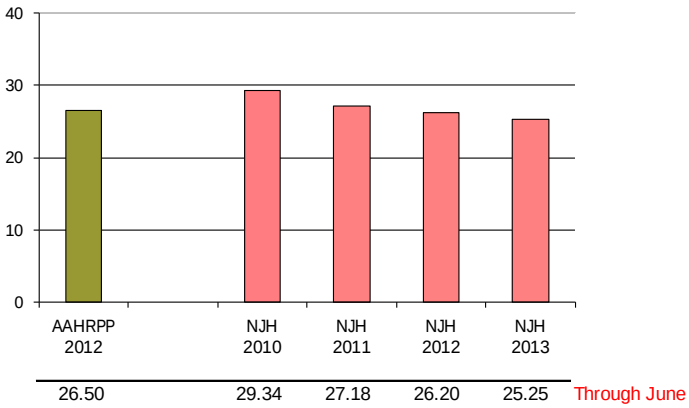
As part of the IRB's ongoing commitment to improve transparency of the review process for submissions, the IRB is providing metrics of its turnaround times as compared to means of hospitals accredited by the Association of the Accreditation of Human Research Protection Programs (AAHRPP).

Below are the 2012 means of other AAHRPP-accredited hospitals and the annual means of the NJH IRB 2010 – 2012. The 2013 column reflects submissions through June.

DAYS TO FULL COMMITTEE REVIEW

COMPARISON TO IRBS WITHIN AAHRPP-ACCREDITED HOSPITALS

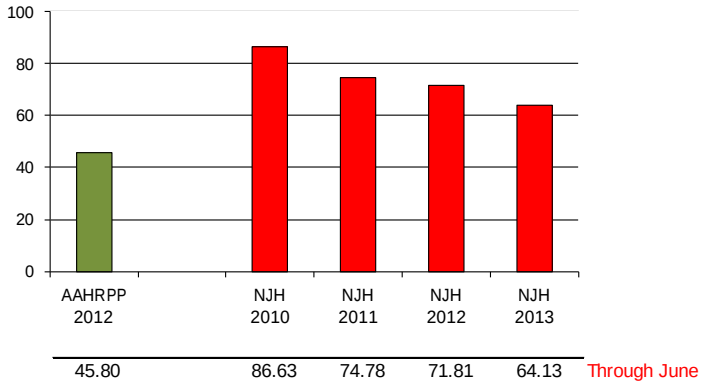
Includes sending stipulations



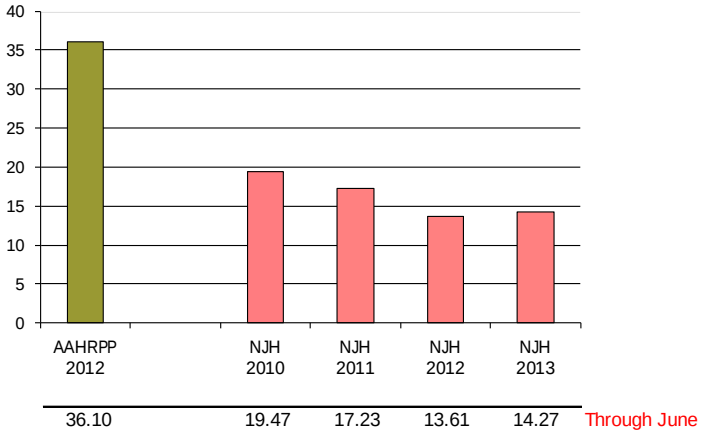
DAYS TO FULL COMMITTEE APPROVAL

COMPARISON TO IRBS WITHIN AAHRPP-ACCREDITED HOSPITALS

Approval includes IRB review time and investigator response time. The NJH IRB does not require investigators to respond to stipulations within a certain time frame.

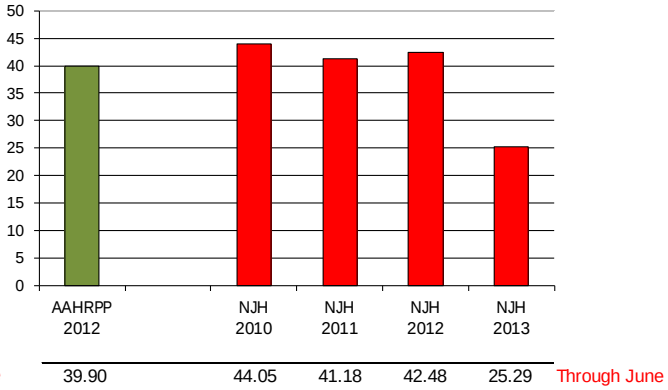


DAYS TO EXPEDITED REVIEW
COMPARISON TO IRBS WITHIN AAHRPP-ACCREDITED HOSPITALS



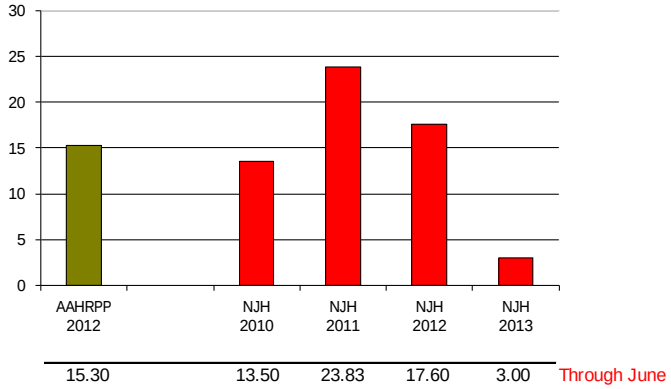
DAYS TO APPROVAL FROM EXPEDITED REVIEW
COMPARISON TO IRBS WITHIN AAHRPP-ACCREDITED HOSPITALS

Approval includes IRB review time and investigator response time. The NJH IRB does not require investigators to respond to stipulations within a certain time frame.



DAYS TO EXEMPT DETERMINATION
COMPARISON TO IRBS WITHIN AAHRPP-ACCREDITED HOSPITALS

Determination includes IRB review time and investigator response time. The NJH does not require investigators to respond to stipulations within a certain time frame.



While AAHRPP only provides metrics about five categories of submissions, the National Jewish Health IRB collects and review metrics for all types of submissions and can even generate reports about submissions by investigator. For initial submissions, the IRB office also tracks dates of interactions between the IRB office and investigators and produces separate metrics for possession time of each party.

Please let us know if there is additional information you would like us to provide.

For more information, contact:
Wendy Charles
charlesw@njhealth.org
303-398-1855

UCD/COMIRB Updates

Wendy Charles

I receive regular updates from COMIRB and the University of Colorado, Denver about educational opportunities on the Anschutz Medical Campus. Nearly all of the lectures, seminars, and workshops are free and open to the public.

If you are interested in receiving alerts about upcoming events, please send an email to me (charlesw@njhealth.org) and I'll add you to my distribution list. You can request to be removed from the distribution list at any time.